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10/578,672	05/09/2006	Annelies Resink	BJS-3665-178	9794

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EXAMINER	
ARCHIE, NINA	
ART UNIT	**PAPER NUMBER**
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/578,672	RESINK ET AL.	
	Examiner	Art Unit	
	Nina A. Archie	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 July 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13-15 and 18-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-15 and 18-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This Office is responsive to Applicant's amendment and response filed 7-27-09. Claims 13-15 and 18-20 are pending and under examination. Claims 16-17 and 21-23 are cancelled.

Objections/Rejections Withdrawn

2. In view of the Applicant's amendments and remarks the following objections/rejections are withdrawn.

a) Objection to the specification, for containing an obvious typographical error. Specifically, encephalopathy is misspelled (see pg. 2 lines 10-15), is withdrawn in light of applicant's argument.

b) Objection to claims 17-19 objected to because of the acronym BSE, is withdrawn in light of applicant's amendment thereto.

c) Rejection to claim 13 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in light of applicant's amendment thereto.

Claim Rejections Maintained

35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Written Description

3. The rejection of claims 13-15 and 18-20 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description are maintained for the reasons set forth in the previous office action.

Applicant arguments:

Applicants arguments filed in response to the 35 U.S.C. 112, first paragraph (written description), July 27, 2009 is carefully considered, but not found to be persuasive for the reasons below.

Applicants states the rejection is based on the recitation of structural variants and analogues, functional analogues, natural variants and polypeptides (see the paragraph spanning pages 4-5 and the first two full paragraph on page 5 of the Office Action dated February 27, 2009), and the amendment obviates the rejection. Applicants state the description of the present specification wherein the DATAS method of marker identification is described and specifically, DATAS identifies qualitative differences in gene expression and provides a systematic analysis of RNA splicing between two conditions : healthy/infected. Applicants state by comparing qualitative gene expression in blood cells from healthy mammals and those infected naturally or experimentally with BSE, different signatures of genetic markers have been isolated. Applicants state the naturally infected animals had terminal stage disease, whereas mammals infected by the oral route with 1 g of BSE-infected brain represent the early stage of the disease. Applicants state implementation of the DATAS method on blood cells from cows led to the identification and isolation of several thousand genetic markers, divided into two libraries representing qualitative gene expression between healthy cows and naturally infected cows, on the one hand, and between healthy cows and experimentally infected cows, on the other hand. Applicants state, the markers in these libraries were selected and validated by two approaches : In the first approach, gene fragments common to the two DATAS libraries produced in this manner were identified and the sequences of these 11 markers are given in sequences SEQ ID NO: 16-26. Applicants state in the second approach, different clones from the two DATAS experiments were transferred to glass slides. The slides were hybridized with probes produced from biological material from naturally or experimentally infected cows and healthy cows used as controls. Applicants argue through the use of two types of statistical analysis, SAM (Significance Analysis of Microarray) and PAM (Prediction Analysis of Microarray), comparing healthy versus infected animals, 15 clones were found to show a deregulation between healthy versus infected conditions. The 15 nucleic acid sequences are described in the specification as SEQ ID NO:1-15.

Examiner's Response to Applicants arguments:

In response to applicant's statements as set forth supra, the amended claims are drawn to any nucleic acid comprising a sequence of SEQ ID NO: 1 or a fragment thereof containing at least 5 consecutive bases and a nucleic acid having a sequence complementary to a sequence above thus any two nucleotides of SEQ I D NO:1 which is not deemed persuasive. Although

applicant has described the use of the two types of statistical analysis, SAM (Significance Analysis of Microarray) and PAM (Prediction Analysis of Microarray), comparing healthy versus infected animals and as a result 15 clones were found to show a deregulation between healthy versus infected conditions, the comparison of healthy versus infected as set forth supra does not detect the presence or the risk of developing a Bovine Spongiform Encephalopathy (BSE) in a bovine or ovine, of a target molecule. Therefore the method of detecting the presence or the risk of developing a Bovine Spongiform Encephalopathy (BSE) in a bovine or ovine, using a target molecule comprising any nucleic acid comprising a sequence of SEQ ID NO: 1 or a fragment thereof containing at least 5 consecutive bases and a nucleic acid having a sequence complementary to a sequence above thus any two nucleotides of SEQ I D NO:1 is not deemed persuasive. Applicants have demonstrated in evidence filed on July 27, 2009 of Applicants arguments that the upregulated gene (SEQ ID NO: 1) is expressed twofold in infected individual and also present in non-infected individuals (see pgs. 12-13). Applicants only provide evidence of using the DATAS method comprises three separate steps : collection of the tissue, isolation of RNA, and creation of a library containing qualitative differences and identifying novel gene fragments, which cannot be isolated by other genetic techniques. However, Applicant has not demonstrated how much DNA of (SEQ ID NO:1) or any fragment thereof such as any nucleic acid comprising a sequence of SEQ ID NO: 1 or a fragment thereof containing at least 5 consecutive bases and a nucleic acid having a sequence complementary to a sequence above thus any two nucleotides of SEQ I D NO:1 is expressed in order to determine the performed outcome as claimed (a method of detecting the presence or the risk of developing a BSE in a bovine or ovine). Moreover, Applicant has not compared the expression level of any nucleic acid comprising a sequence of SEQ ID NO: 1 or a fragment thereof containing at least 5 consecutive bases and a nucleic acid having a sequence complementary to a sequence above thus any two nucleotides of SEQ I D NO:1 in an infected vs. healthy individual to detect the presence of BSE much less the risk of developing BSE. Therefore any nucleic acid comprising a sequence of SEQ ID NO: 1 or a fragment thereof containing at least 5 consecutive bases and a nucleic acid having a sequence complementary to a sequence above thus any two nucleotides of SEQ I D NO:1 cannot be used, alone or in combination(s), to detect, characterize or monitor a transmissible spongiform encephalopathy in a mammal and in particular, to detect the presence of prion

diseases in mammalian subjects, particularly ovines, bovines and humans. Furthermore, eventhough the specification specifically discloses SEQ ID NO: 1 as being a genetic marker and the gene has been identified in evidence filed on July 27, 2009 of Applicants arguments, Applicants have not shown the correlation of SEQ ID NO: 1 or any two nucleotides of SEQ ID NO:1 (or any fragment, complement etc.). Therefore any nucleic acid comprising a sequence of SEQ ID NO: 1 or a fragment thereof containing at least 5 consecutive bases and a nucleic acid having a sequence complementary to a sequence above thus any two nucleotides of SEQ I D NO:1 with the function as presently claimed is not deemed persuasive given that the gene is not identified and there is no correlation that can be made with regard to the presence of an encephalopathy much less the risk of developing an encephalopathy.

As outlined previously in the written description rejection, the claims are drawn to a method of detecting the presence or the risk of developing a BSE in a bovine or ovine, comprising determining the presence, in a biological sample from the bovine or ovine, of a target molecule selected in the group consisting of: a) a nucleic acid comprising a sequence of SEQ ID NO: 1 or a fragment thereof containing at least 5 consecutive bases, and b) a nucleic acid having a sequence complementary to a sequence according to a) the presence of said target molecule in the sample being an indication of the presence or the risk of developing BSE in said bovine or ovine.

The specification states “through extensive research based on an innovative approach, different additional BSE markers have been identified and validated by hybridization experiments, enabling the development of a presymptomatic test that can be used on blood from a live mammal". The specification states that the identified marker was given in sequences such as SEQ ID NO: 1 (see pg. 2 lines 10-15). Additionally clones were hybridized with probes produced from biological material from naturally or experimentally infected cows and healthy cows used as controls. As a result 15 clones were found to show a deregulation between healthy versus infected condition. Thus SEQ ID NO: 1 is purportedly able to detect deregulation between healthy versus infected condition. However no marker, including SEQ ID NO: 1 has been demonstrated to detect the presence or the risk of developing an encephalopathy in a mammal. SEQ ID NO: 1 is a genetic marker that is derived from Bovine Spongiform

Encephalopathy. Even though the specification specifically discloses SEQ ID NO: 1 as being a genetic marker the gene has not been identified. The specification does not disclose any other information on the gene SEQ ID NO: 1 regarding its claimed function (detecting an encephalopathy or the risk of developing one). Furthermore, the specification does not disclose the expression level or if any expression level exists of SEQ ID NO: 1 (or any fragment, complement etc.) in a healthy individual. As a result Applicant has not shown the correlation of SEQ ID NO: 1 (or any fragment, complement etc.) with the function as directed with the aforementioned above, given that the gene is not identified and there is no correlation that can be made with regard to the presence of an encephalopathy much less the risk of developing an encephalopathy.

Moreover, the scope of the claims includes numerous structural variants/analogues, and the genus is highly variant because a significant number of structural differences between genus members are permitted. Furthermore the scope of the claim includes a nucleic acid having a sequence complementary to SEQ ID NO: 1 and a polypeptide coded by SEQ ID NO: 1 being an indication of the presence or the risk of developing an encephalopathy in said mammal. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, using target molecules to detect the presence or the risk of developing an encephalopathy in said mammal alone is insufficient to describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, applicant was not in possession of the claimed genus.

As to the aforementioned method, the claims are drawn to a large number functional analogue of variants and a polypeptide coded by variants having different possibilities of changes to the amino acid sequence of SEQ ID NO: 1. The specification does not teach an example of any functional analogue of variants and a polypeptide coded by variants that comprise the method of detecting the presence or the risk of developing an encephalopathy in a mammal.

Without disclosure of a) a nucleic acid comprising a sequence of SEQ ID NO: 1 or a fragment thereof containing at least 5 consecutive bases, and b) a nucleic acid having a sequence complementary to a sequence according to a) the presence of said target molecule in the sample

being an indication of the presence or the risk of developing BSE in said bovine or ovine; the written description is not deemed to be fulfilled and the specification lacks proper written description of the claimed method as set forth *supra*. This issue is best resolved by Applicants pointing to the specification by page and line number where description of the claimed invention is set forth. Therefore, absent a detailed and particular description of a representative number, or at least a substantial number of the members of the genus of a) a nucleic acid comprising a sequence of SEQ ID NO: 1 or a fragment thereof containing at least 5 consecutive bases, and b) a nucleic acid having a sequence complementary to a sequence according to a) the presence of said target molecule in the sample being an indication of the presence or the risk of developing BSE in said bovine or ovine, the presence of said target molecule in the sample being an indication of the presence or the risk of developing BSE in bovine or ovine, the skilled artisan could not immediately recognize or distinguish members of the claimed genus of antigens. Therefore, in accordance with the Guidelines, the description is not deemed representative and thus does not meet the written description requirement.

Applicants are directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, 1 "Written Description" Requirement, Federal Register, Vol. 64, No. 244, pages 71427-71440, Tuesday December 21, 1999.

Enablement

4. The rejection of claims 13-15 and 18-20 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement are maintained for the reasons set forth in the previous office action.

Applicant arguments:

Applicants arguments filed in response to the 35 U.S.C. 112, first paragraph (enablement), July 27, 2009 is carefully considered, but not found to be persuasive for the reasons below.

Applicants state the following supplementary experimental data shows by SAM and PAM analysis that SEQ ID NO: 1 is specific for infected animals. Applicant state the plots of the probability density functions of the normalized log-ratios of EXB-NROA0576 (SEQ ID NO: 1) reveal a clear separation (with no overlap at all) between the expression levels of the non-

infected and infected populations using this gene. Applicants state SEQ ID NO: 1 (EXB-NROA0576 gene, Homo sapiens serine/threonine kinase 24, STK24, STE20 homolog, yeast) is a marker for detecting BSE. Applicants disclose a preparation of BSE microarray slide to identify diagnostic markers that differentiate RNA samples taken from blood of infected animals versus RNA from blood of control animals (see pg. 10 of Applicants Arguments filed July 27, 2009). Applicants disclose a preparation of hybridization probes cRNA and hybridizations and analysis on 6 naturally infected and 5 non infected samples and software SAM and PAM was applied to the 818 genes and among these 818 genes, STK24 gene (i.e., SEQ ID NO: 1) was identified as the most upregulated gene (by two fold) (see pgs. 12-13 of Applicants Arguments filed July 27, 2009).

Examiner's Response to Applicants arguments:

In response to applicant's statements as set forth supra, the evidence provided in Applicants arguments filed on July 27, 2009 should be stated in the form of a declaration. Although applicant has provided experimental data on analysis of SAM and PAM that SEQ ID NO: 1 is specific for infected animals, said experimental data as set forth supra is not deemed persuasive and therefore the claimed invention is not enabled for a method of detecting of the presence or the risk of developing a Bovine Spongiform Encephalopathy (BSE) in a bovine or ovine using a target molecule comprising any nucleic acid comprising a sequence of SEQ ID NO: 1 or a fragment thereof containing at least 5 consecutive bases and a nucleic acid having a sequence complementary to a sequence and thus any two nucleotides of SEQ I D NO:1. In regards, to the experimental data aforementioned above, Applicant has not demonstrated how much DNA of (SEQ ID NO:1) or any fragment thereof such as any nucleic acid comprising a sequence of SEQ ID NO: 1 or a fragment thereof containing at least 5 consecutive bases and a nucleic acid having a sequence complementary to a sequence above thus any two nucleotides of SEQ I D NO:1 is expressed in order to determine the performed outcome as claimed (a method of detecting the presence or the risk of developing a BSE in a bovine or ovine). Applicant has not compared the expression level of any nucleic acid comprising a sequence of SEQ ID NO: 1 or a fragment thereof containing at least 5 consecutive bases and a nucleic acid having a sequence complementary to a sequence above thus any two nucleotides of SEQ I D NO:1 in an infected vs.

healthy individual to detect the presence of BSE much less the risk of developing BSE. Therefore any nucleic acid comprising a sequence of SEQ ID NO: 1 or a fragment thereof containing at least 5 consecutive bases and a nucleic acid having a sequence complementary to a sequence above thus any two nucleotides of SEQ I D NO:1 cannot be used, alone or in combination(s), to detect, characterize or monitor a transmissible spongiform encephalopathy in a mammal and in particular, to detect the presence of prion diseases in mammalian subjects, particularly ovines, bovines and humans. Therefore the rejection is maintained.

As outlined previously in the enablement rejection, the specification is not enabled for any method of detecting the presence or the risk of developing a Bovine Spongiform Encephalopathy (BSE) in a bovine or ovine, comprising determining the presence, in a biological sample from the bovine or ovine, of a target molecule selected in the group consisting of: a) a nucleic acid comprising a sequence of SEQ ID NO: 1 or a fragment thereof containing at least 5 consecutive bases, and b) a nucleic acid having a sequence complementary to a sequence according to a) the presence of said target molecule in the sample being an indication of the presence or the risk of developing BSE in said bovine or ovine.

Enablement is considered in view of the Wands factors (MPEP 2164.01(a)). There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." These factors include, but are not limited to:

(A) The breadth of the claims;
(B)The nature of the invention;
(C)The state of the prior art;
(D)The level of one of ordinary skill;
(E)The level of predictability in the art;
(F)The amount of direction provided by the inventor;
(G)The existence of working examples; and
(H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Nature of the invention

The claims are drawn to a method of detecting the presence or the risk of developing a BSE in a bovine or ovine, comprising determining the presence, in a biological sample from the bovine or ovine, of a target molecule selected in the group consisting of: a) a nucleic acid comprising a sequence of SEQ ID NO: 1 or a fragment thereof containing at least 5 consecutive bases, and b) a nucleic acid having a sequence complementary to a sequence according to a) the presence of said target molecule in the sample being an indication of the presence or the risk of developing BSE in said bovine or ovine.

The breadth of the claims

The product being used to detect the presence or the risk of developing a BSE in a bovine or ovine consisting:

a) a nucleic acid comprising a sequence of SEQ ID NO: 1 or a fragment thereof containing at least 5 consecutive bases;

b) a nucleic acid having a sequence complementary to a sequence according to a) the presence of said target molecule in the sample being an indication of the presence or the risk of developing BSE in said bovine or ovine.

The Quantity of Experimentation Required

The quantity of experimentation required to practice the invention as claimed would be undue as it would require novel and unknown species that will correlate to the method as set forth *supra* to detect the presence detecting the presence or the risk of developing BSE in a bovine or ovine. Since the specification fails to provide particular guidance for detecting the presence of or the risk of developing an encephalopathy as set forth supra it would require undue experimentation to practice the invention over the broad scope as presently claimed.

Guidance in the specification

The specification states “through extensive research based on an innovative approach, different additional BSE markers have been identified and validated by hybridization

experiments, enabling the development of a presymptomatic test that can be used on blood from a live mammal". The specification states that the identified marker was given in sequences such as SEQ ID NO: 1 (see pg. 2 lines 10-15). Additionally clones were hybridized with probes produced from biological material from naturally or experimentally infected cows and healthy cows used as controls. As a result 15 clones were found to show a deregulation between healthy versus infected condition. Thus SEQ ID NO: 1 is purportedly able to detect deregulation between healthy versus infected condition. However no marker, including SEQ ID NO: 1 has been demonstrated to detect the presence or the risk of developing an encephalopathy in a mammal. SEQ ID NO: 1 is a genetic marker that is derived from Bovine Spongiform Encephalopathy. Even though the specification specifically discloses SEQ ID NO: 1 as being a genetic marker the gene has not been identified. The specification does not disclose any other information on the gene SEQ ID NO: 1 regarding its claimed function (detecting an encephalopathy or the risk of developing one). Furthermore, the specification does not disclose the expression level or if any expression level exists of SEQ ID NO: 1 (or any fragment, complement etc.) in a healthy individual. As a result Applicant has not shown the correlation of SEQ ID NO: 1 (or any fragment, complement etc.) with the function as directed with the aforementioned above, given that the gene is not identified and there is no correlation that can be made with regard to the presence of an encephalopathy much less the risk of developing an encephalopathy.

Moreover, the scope of the claims includes numerous structural variants/analogues, and the genus is highly variant because a significant number of structural differences between genus members are permitted. Furthermore the scope of the claim includes a nucleic acid having a sequence complementary to SEQ ID NO: 1 and a polypeptide coded by SEQ ID NO: 1 being an indication of the presence or the risk of developing an encephalopathy in said mammal. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, using target molecules to detect the presence or the risk of developing an encephalopathy in said mammal alone is insufficient to describe the genus. As to the aforementioned method, the claims are drawn to a large number functional analogue of variants and a polypeptide coded by variants having different possibilities of changes to the amino acid sequence of SEQ ID NO: 1. The specification does not teach an

example of any functional analogue of variants and a polypeptide coded by variants that comprise the method of detecting the presence or the risk of developing an encephalopathy in a mammal.

Therefore, the specification as filed fails to provide particular guidance demonstrating a reasonable extrapolation with method of detecting the presence as set forth supra.

Working examples

The specification does not provide any working examples of any of the claimed target molecules being able to perform the function set forth in the preamble of the claim.

In conclusion, the claimed inventions are not enabled for a method of detecting the presence as set forth supra consisting of: a) a nucleic acid comprising a sequence of SEQ ID NO: 1 or a fragment thereof containing at least 5 consecutive bases, and b) a nucleic acid having a sequence complementary to a sequence according to a) the presence of said target molecule in the sample being an indication of the presence or the risk of developing BSE in said bovine or ovine. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with the claimed invention. The products being used to detecting the presence or the risk of developing a BSE in a bovine or ovine as set forth supra is overly broad. Furthermore, Applicant has not disclosed a complementary sequence of SEQ ID NO: 1 in step b) which will encode a different protein to detect the presence or the risk of developing BSE in a bovine or ovine. As a result, for the reasons discussed above, it would require undue experimentation for one skilled in the art to use the claimed methods.

Conclusion

4. No claims are allowed.

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply

is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nina A. Archie whose telephone number is 571-272-9938. The examiner can normally be reached on Monday-Friday 8:30-5:00p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner supervisor, Robert Mondesi can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nina A Archie
Examiner
GAU 1645
REM 3B31

/Robert A. Zeman/
for Nina Archie, Examiner of Art Unit 1645